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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

<u>MEMORANDUM</u>

SUBJECT:

Chlorothalonil & HCB: ISK Biotech Response to 7/31/91 Chlorothalonil DCI: Guideline 171-5,

Reduction in Residues: CBRS No 10462: DP Barcode

D181909.

FROM:

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THROUGH:

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TO:

Lois Rossi/Andrew Ertman Reregistration Branch

Special Review & Reregistration Division (H7508W)

CBRS has been asked to evaluate ISK Biotech's response to guideline 171-5, Reduction in Residues, as contained in the 7/31/91 Chlorothalonil DCI. This requirement was triggered by unacceptably high dietary risk estimates for chlorothalonil assuming tolerance levels residues in or on raw agricultural commodities. Both chlorothalonil and hexachlorobenzene, a contaminant in chlorothalonil formulations, are B2 carcinogens. It is the registrant's responsibility to provide the Agency with data indicating reduction in residues on food commodities due to washing, cooking or other normal processing that may occur between the farm gate and the time of consumption in order to gain a more realistic estimate of the dietary risk incurred by using this pesticide.

REGISTRANT'S RESPONSE TO 7/31/91 DCI

The registrant has submitted an analysis of chronic dietary exposure to residues of chlorothalonil and its manufacturing impurity hexachlorobenzene resulting from the use of chlorothalonil on all currently registered crops plus almonds, asparagus, blueberries, mangoes and mushrooms (MRID 42272101). This analysis was performed for the registrant by Technical Assessment Systems, Inc. Processing factors that are included in

this analysis are listed in Table 1. This information suggests that residues of chlorothalonil are significantly reduced when raw agricultural commodities are washed and cooked. However, CBRS has not reviewed the data used to estimate the "processing factors" shown in Table 1, and defers judgement on the adequacy of this information until the dietary exposure for this pesticide is reassessed.

Table 1. Processing factors used by registrant in estimating chronic dietary exposure to residues of chlorothalonil resulting from its use on agricultural commodities (MRID 42272101).

COMMODITY	PROCESSED FORM	FACTOR ¹
Beans, Succulent	heated	0.02
Beans, Succulent	frozen	0.03
Cabbage		0.15
Cabbage, Chinese		0.19
Carrots	cooked	0.005
Cherries	cooked	0.01
Cucumbers	washed	0.53
Cucumbers	cold canned pickles	0.095
Cucumbers	hot canned pickles	0.014
Peaches	washed	0.04
Peaches	canned	0.001
Peanuts	refined oil	0.67
Potatoes	washed	0.72
Potatoes	peels	12.14
Pumpkin	partially cooked	0.001
Pumpkin	peeled	0.002
Squash, Winter	partially cooked	0.005
Tomatoes	processed whole tomatoes	0.58
Tomatoes	juice	0.04
Tomatoes	concentrates	0.01

^{1.} The processing factor is the ratio of the residue in the processed commodity to the residue in the raw commodity.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

The registrant has informed the Agency that they are improving their production process for chlorothalonil resulting in a reduction in HCB contamination in technical chlorothalonil by at No confirming product chemistry data have been submitted to the Agency.

CBRS COMMENTS AND CONCLUSIONS

No further data will be required at this time for Guideline number 171-5, reduction in residues, contingent upon the registrant submitting product chemistry data to document their reduction of HCB in chlorothalonil formulations. However, CBRS defers comment on the chronic dietary risk analysis as provided by the registrant until receipt of outstanding data concerning the residues of HCB in ruminants from the use of chlorothalonil on feed items, and until dietary exposure for this pesticide is reassessed. The registrant should be aware that we may require further residue reduction data in the future.

cc: W. Smith, Chlorothalonil Reg. Std. File, SF, RF, circulation.

H7509C:CB-II:WOS:wos:Rm805A:CM#2:X5353:10/07/92 RDI: PDeschamp(11/13/92) MMetzger(11/13/92)